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09/559,401	04/26/2000	Hiroyuki Yuyama	2000 0523A	1206

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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/559,401

Applicant(s)

YUYAMA ET AL.

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. In the amendment filed 9/30/04, the following has occurred: claim 10 has been amended. Now, claims 10-18 are presented for examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 10, 12, 14, 15, and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Bloom et al., U.S. Patent No. 6,070,761.
4. As per claim 10, Engleson teaches an apparatus for supporting injection mixing work, said apparatus comprising: a memory operable to store data for supporting injection mixing work, said memory being operable to store a patient predictability data file for storing patient predictability data including at least patient predictable information (see column 5, line 66 – column 6, line 2), an injection prescription data file for storing injection prescription data corresponding to the patient predictability data (see column 6, lines 2-6), and a combination related data file for storing combination related data corresponding to each injection of the injection prescription data (see column 6, lines 54-58); a display operable display the data stored in said memory (see column 2, lines 28-31); and a controller operable to determine a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, and to display the determined mixing order on said display (see column 8, line 66 – column 9, line 12 and Figure 9). Engleson does not explicitly teach

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determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection and that a mixing order is determined by the controller before the injections are dosed to the patient. Bloom teaches a system that supports delivery of intravenous drugs that includes determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection and that a mixing order is determined by the controller before the injections are dosed to the patient (see column 33, lines 45-59). It would have been obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate these features into the system of Engleson. One of ordinary skill in the art would have been motivated to incorporate these features for the purpose of enhancing patient safety when prescribing injections of a plurality of different drugs.

5. As per claim 12, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson further teaches the combination related data file of said memory includes differentiation data for differentiating transfusion and solely administrated medicament, and wherein said controller is operable to classify the injection contained in the injection prescription data for a patient into transfusion or solely administrated medicament in accordance with the differentiation data and displays it on the display (see column 9, lines 40-52).

6. As per claim 14, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson further teaches the combination related data file of said memory stores attention information data related to each injection, and wherein the controller is operable to display an attention information in the attention information data on the display corresponding to each injection of the injection prescription data (see column 9, lines 63-67).

7. As per claim 15, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson further teaches a reader operable to read an identification code for

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identifying each injection, wherein said controller is operable to display a progress situation of mixing work on said display in accordance with the identification code read by the reader when conducting the mixing work of the injection (see column 7, lines 44-52).

8. As per claim 18, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson further teaches a reader operable to read a prescription identification code for identifying each injection prescription data, wherein said controller is operable to read the corresponding injection prescription data in accordance with the prescription identification code and displays it on the display (see column 7, lines 44-52).

9. Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Bloom et al., U.S. Patent No. 6,070,761 and further in view of Merki et al., U.S. Patent No. 5,002,055.

10. As per claim 11, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson does not explicitly teach storing pH-values data for each injection and determining the mixing order of the injections in accordance with the pH-values data. Merki teaches storing pH-values data for injections, and wherein a controller decides a mixing order of the injections in accordance with the pH-values (see column 3, lines 52-63). It would have been obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate this feature into the system of Engleson. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety by regulating pH-values.

11. As per claim 16, Engleson in view of Bloom teach the apparatus of claim 15 as described above. Engleson further teaches the controller decides whether the injection is proper or not in accordance with the identification code of the injection read by the reader and if

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improper, displays it on the display (see column 7, lines 52-59). Engleson does not explicitly teach storing pH-values data for each injection and determining the mixing order of the injections in accordance with the pH-values data. Merki teaches storing pH-values data for injections, and wherein a controller decides a mixing order of the injections in accordance with the pH-values (see column 3, lines 52-63). It would have been obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate this feature into the system of Engleson. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety by regulating pH-values.

12. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Bloom et al., U.S. Patent No. 6,070,761 and further in view of Mayaud, U.S. Patent No. 5,845,255.

13. As per claim 4, Engleson in view of Bloom teach the apparatus of claim 1 as described above. Engleson does not explicitly teach storing incompatibility data for showing whether or not two kinds of injections are incompatible and displaying the incompatibility on the display. Mayaud teaches storing incompatibility data showing whether or not a combination of two kinds of injections is incompatible, and wherein the controller decides whether or not a combination of two kinds of injections contained in injection prescription data for a patient is incompatible in accordance with the incompatibility data and displays it on a display (see column 31, lines 19-24). It would have been obvious to one of ordinary skill in the art of prescription management at the time of the invention to incorporate the incompatibility detection feature of Mayaud into the invention of Engleson. One of ordinary skill in the art would have been motivated to make such

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a combination for the purpose of enhancing patient safety when prescribing injections of a plurality of different drugs.

14. As per claim 8, Engleson in view of Bloom and Mayaud teach the system of claim 4 as describe above. Engleson does not explicitly teach inputting new incompatibility data and storing it in the combination related data of the memory. Mayaud teach inputting new incompatibility data in addition to stored incompatibility data and storing it in a combination related data in memory (see column 31, lines 33-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to make add this feature to the system of Engleson for the reasons given above with respect to claim 4.

Response to Arguments

15. In the remarks filed 9/30/04, Applicants argue in substance that (1) the medical administration management module in Engleson is not operable to determine a mixing order of the injections; (2) the combination related data file of Engleson is not used for determining an incompatibility or mixing order; (3) Bloom does not teach a controller which is operable to determine, before injections are dosed to a patient, a mixing order of the injections.

16. In response to Applicants' argument (1), the Examiner respectfully disagrees with this interpretation of Engleson. The system of Engleson includes a controller that determines and displays the mixing order of injections for various patients. Examples of this are clearly shown in Figures 9 and 10 which show a mixing order of injections in accordance with data corresponding to each injection. To further support the argument, Applicants argue at pages 8 and 9 of the Remarks that "the medications that are visually displayed on the display screen are not determined by the medical administration management module 110 but are merely a reflection of either the order in which the medications are entered into the system or the order in

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which a physician prescribed the medications.” However, the Examiner respectfully reminds Applicants that the claims merely require that an order of injections contained in the injection prescription data is determined by a controller in accordance with the combination related data. Furthermore, the combination related data is merely limited to data corresponding to each injection. Engleson very clearly teaches that a mixing order is determined in accordance with patient data and injection data and displayed on a screen as shown in Figures 8 and 9. The fact that this output is used to assist nurses or other health care professionals in care deliver, as asserted by Applicants, does not change the fact that the medical administration management module determines the mixing order in accordance with the identified input data.

17. In response to Applicants’ argument (2), the Examiner again respectfully disagrees with this interpretation of Engleson. As described above in response to argument (1), the combination related data is merely limited to data corresponding to each injection. Furthermore, data corresponding to each injection is clearly used in determining a mixing order for display on an output as shown in Figures 8 and 9 of Engleson.

18. In response to Applicants’ argument (3), the Examiner refers to the above cited portions of Bloom. The cited portion describes the process by which the system of Bloom determines mixing and delivery parameters and displays them on a display. The clinician then has the option to change the parameters, however, the changes must conform to the minimum and maximum recommendations set forth in the pharmaceutical database. This clearly occurs before injections are dosed to a patient and, therefore, the Examiner disagrees with Applicants’ interpretation of the teachings of this reference.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (703) 308-6104. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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CLG
12/16/04


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